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Attorney Docket No. P31831C1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Stephen A. Smith	August 13, 2001
Serial No.:	Not Assigned	Group Art Unit No.: Not Assigned
Filed:	Herewith	Examiner: Not Assigned
For:	TREATMENT OF DIABETES WITH ROSIGLITAZONE AND INSULIN	

**PRELIMINARY AMENDMENT**

Preliminary to the examination of this application, Applicants respectfully request amendment of the above-identified application as follows:

**In the specification:**

Kindly add the Abstract enclosed herewith on a separate sheet, at the end.

**In the claims:**

Please delete claim 12.

Please amend claims 1, 3-11 and 13 as follows:

1. (Amended) A method for the treatment of diabetes mellitus and conditions associated with diabetes mellitus in a mammal, which method comprises administering an effective non-toxic and pharmaceutically acceptable amount of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (Compound I) and insulin, to a mammal in need thereof.
3. (Amended) A method according to claim 2, which comprises the administration of 2 to 12 mg of Compound (I).
4. (Amended) A method according to claim 3, which comprises the administration of 2 to 4, 4 to 8 or 8 to 12 mg of Compound (I).
5. (Amended) A method according to claim 4, which comprises the administration of 2 to 4mg of Compound (I).
6. (Amended) A method according to claim 4, which comprises the administration of 4 to 8mg of Compound (I).

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7. (Amended) A method according to claim 4, which comprises the administration of 8 to 12 mg of Compound (I).

8. (Amended) A method according to claim 5, which comprises the administration of 2 mg of Compound (I).

9. (Amended) A method according to claim 5, which comprises the administration of 4 mg of Compound (I).

10. (Amended) A method according to claim 6, which comprises the administration of 8 mg of Compound (I).

11. (Amended) A pharmaceutical composition comprising 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (Compound I), insulin and a pharmaceutically acceptable carrier therefor.

13. (Amended) A composition according to claim 11, which comprises up to 12 mg or 2 to 12 mg of Compound (I).


#### **REMARKS**

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Applicants have amended the claims to put them in conformity with the U.S. practice.

No new matter has been introduced.

Respectfully submitted,

  
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the specification:**

An Abstract of the Invention has been added.

**In the claims:**

1. (Amended) A method for the treatment of diabetes mellitus and conditions associated with diabetes mellitus in a mammal, which method comprises administering an effective non-toxic and pharmaceutically acceptable amount of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (Compound [(I)] and insulin, to a mammal in need thereof.
3. (Amended) A method according to [claim 1or] claim 2, which comprises the administration of 2 to 12 mg of Compound (I).
4. (Amended) A method according to [any one of] claim[s 1 to] 3, which comprises the administration of 2 to 4, 4 to 8 or 8 to 12 mg of Compound (I).
5. (Amended) A method according to [any one of] claim[s 1 to 3] 4, which comprises the administration of 2 to 4mg of Compound (I).
6. (Amended) A method according to [any one of] claim[s 1 to 3] 4, which comprises the administration of 4 to 8mg of Compound (I).
7. (Amended) A method according to [any one of] claim[s 1 to 3] 4, which comprises the administration of 8 to 12 mg of Compound (I).
8. (Amended) A method according to [any one of] claim[s 1 to 3] 5, which comprises the administration of 2 mg of Compound (I).
9. (Amended) A method according to [any one of] claim[s 1 to 3] 5, which comprises the administration of 4 mg of Compound (I).
10. (Amended) A method according to [any one of] claim[s 1 to 3] 6, which comprises the administration of 8 mg of Compound (I).

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11. (Amended) A pharmaceutical composition comprising 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (Compound [(II)], insulin and a pharmaceutically acceptable carrier therefor.

13. (Amended) A composition according to claim 11 [or claim 12], which comprises up to 12 mg or 2 to 12 mg of Compound (I).

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